

ACCELERATED DARK SPOT CORRECTOR- hydroquinone cream
COSMETIC ENTERPRISES LTD

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Dark Spot Corrector

Active Ingredients	Purpose
Hydroquinone 2.0%	Skin Lightener

Uses

- lightens dark spots in the skin, such as freckles, age and liver spots, or pigment in the skin that may occur in pregnancy or from the use of oral contraceptives

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if skin rash occurs

Warnings

For external use only

When using this product

- avoid direct contact with eyes
- some users of this product may experience a mild skin irritation
- if skin irritation becomes severe, stop use and consult a physician
- do not use on children under 12 years of age unless directed by a physician
- sun exposure should be limited by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring
- avoid overuse of hydroquinone which has been associated with a rare skin condition called ochronosis

Directions

- adults apply a small amount as a thin layer over face, neck, and chest in the evening, or use as directed by a physician
- if no improvement is seen after three months of treatment, use of this product should be discontinued
- lightening effect of this product may not be noticeable when used on very dark skin
- for children under 12 years of age, do not use unless directed by a physician.

Water (Aqua), C12-15 Alkyl Benzoate, Butylene Glycol, Ethoxydiglycol, Stearyl Alcohol, Glyceryl Stearate, Cetyl Alcohol, Tocopheryl Acetate, Panthenol, Allantoin, Dimethicone, Squalane, Steareth-21, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Crosspolymer, Polysorbate 60, Steareth-2, Phenoxyethanol, Sodium Bisulfite, Sorbic Acid, Citric Acid, Disodium EDTA

SPECIFIC BEAUTY

ACCELERATE

DARK SPOT CORRECTOR

2.0% Hydroquinone Skin Lightener

0.5 FL. OZ. / 15 mL

**DERMATOLOGIST
STRENGTH
FORMULA**

TO USE: *Kick start your results by using once daily for 7-14 days, in the evening.* After using the Advanced Dark Spot Corrector Pads, apply to the affected areas, avoiding the eye area. Discontinue after 14 days for a period of 2-3 months.

ACTIVE INGREDIENT:
Hydroquinone 2.0%

WARNING: For external use only. Avoid contact with eyes. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

For full product information, please refer to Drug Facts Panel.

Questions or Comments?
1-800-325-3654 or
SpecificBeauty.com

DISTRIBUTED BY:
JUNEE Brands, LLC
Los Angeles, CA 90049

5B0007

**SPECIFIC
BEAUTY™**



**ACCELERATED
DARK SPOT CORRECTOR
2.0% Hydroquinone Skin Lightener**

0.5 FL. OZ. / 15 mL

ACCELERATED DARK SPOT CORRECTOR

Drug Facts	
Active ingredients Hydroquinone 2.0%.....	Purpose Skin Lightener
Use ■ lightens dark spots in the skin, such as freckles, age and liver spots, or pigment in the skin that may occur in pregnancy or from the use of oral contraceptives.	
Warnings For external use only	
When using this product ■ avoid direct contact with eyes ■ some users of this product may experience a mild skin irritation ■ if skin irritation becomes severe, stop use and consult a physician ■ do not use on children under 12 years of age unless directed by a physician ■ sun exposure should be limited by using a sunscreen agent, a sun blocking agent, or protective clothing to cover bleached skin when using and after using this product in order to prevent darkening from reoccurring ■ avoid overuse of hydroquinone which has been associated with a rare skin condition called ochronosis.	
Stop use and ask a doctor if ■ skin rash occurs	
Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.	
Directions ■ adults apply a small amount as a thin layer over face, neck and chest in the evening, or use as directed by a physician ■ if no improvement is seen after three months of treatment, use of this product should be discontinued ■ lightening effect of this product may not be noticeable when used on very dark skin ■ for children under 12 years of age, do not use unless directed by a physician.	
Inactive ingredients Water (Aqua), C12-15 Alkyl Benzoate, Butylene Glycol, Ethoxydiglycol, Stearyl Alcohol, Glyceryl Stearate, Cetyl Alcohol, Tocopheryl Acetate, Panthenol, Allantoin, Dimethicone, Squalane, Steareth-21, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Polysorbate 60, Steareth-2, Phenoxyethanol, Sodium Bisulfite, Sorbic Acid, Citric Acid, Disodium EDTA.	
Questions or comments? 1-800-976-7812 SpecificBeauty.com	

ACCELERATED DARK SPOT CORRECTOR			
hydroquinone cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56 152-5005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROQUINONE (UNII: XV74C1N1AE) (HYDROQUINONE - UNII:XV74C1N1AE)	HYDROQUINONE	2 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PANTHENOL (UNII: WV9CM0O67Z)	
ALLANTOIN (UNII: 344S277G0Z)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SQUALENE (UNII: 7QWM220FJH)	
STEARETH-21 (UNII: 53J3F32P58)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPAS AT 1.5%) (UNII: 86FQE96TZ4)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
STEARETH-2 (UNII: V56DFE46J5)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM BISULFITE (UNII: TZX5469Z6I)	
SORBIC ACID (UNII: X045WJ989B)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56152-5005-2	1 in 1 BOX	06/12/2017	
1	NDC:56152-5005-1	15 mL in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part358A	06/12/2017	

Labeler - COSMETIC ENTERPRISES LTD (017701475)**Registrant** - COSMETIC ENTERPRISES LTD (017701475)

Establishment			
Name	Address	ID/FEI	Business Operations
COSMETIC ENTERPRISES LTD		017701475	manufacture(56152-5005)

Revised: 6/2017

COSMETIC ENTERPRISES LTD